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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,559	11/30/2004	Eric David Moher	X-14978M	7051
25885 7590 08/27/2007 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER JARRELL, NOBLE E	
			ART UNIT 1624	PAPER NUMBER
			NOTIFICATION DATE 08/27/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	Application No. 10/516,559	Applicant(s) MOHER ET AL.	
	Examiner Noble Jarrell	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38,42-46,49-53,59,66,68,71 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46 and 52-53 is/are allowed.
- 6) ☒ Claim(s) 38,42,43,49-51,59,66,68,71 and 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Status of Application**

1. The Amendment-After Non-Final Rejection received July 2, 2007 has been acknowledged and fully considered. Claims 38, 42-46, 49-53, 59, 66, 68, 71, and 73-75 are currently pending in the application.

### Rejections and Objections Withdrawn

#### ***Response to Arguments***

2. Applicant's arguments, see page 9, paragraph 3, filed July 2, 2007, with respect to the information disclosure statement have been fully considered and are persuasive. The objection of 4/2/2007 has been withdrawn.
3. Applicant's arguments, see page 9, paragraph 2, filed July 2, 2007, with respect to the 103(a) rejection have been fully considered and are persuasive. The rejection of 4/2/2007 has been withdrawn.
4. Applicant's arguments, see page 10, filed July 2, 2007, with respect to the rejection(s) of claim(s) 38-46 and 64-74 under 35 U.S.C. 112 1st paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendments made in claim 38 and 50.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 38, 59, 66, 68, 71, 73-75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The last possibility of variable A, "amino acids in which the

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$\alpha$ -carbon bears two side-chain substituents", is vague. What side-chains are being referred to? One interpretation is any amino acid (natural or unnatural) besides glycine. Applicants do not provide any guidance for what this possibility can represent.

Rejections Maintained

***Response to Arguments***

7. Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive. Claims 38, 42-43, and 49-51 stand rejected for the reasons of record under 35 U.S.C. 102(e). Applicants argue that Johnson et al. do not explicitly say that LY 404039 is a peptidyl prodrug. However, since the structure is known in the art, Johnson et al. do not have to explicitly state what the compound is. Therefore, claims 38, 42-43, and 49-51 are rejected. Claims 49 and 51 are rejected because Johnson et al. teach that amines of the invention and can react with any number of inorganic and organic acids to form acid addition salts (page 11, lines 9-29). Hydrochloride and tosylate salts are two examples mentioned. Thus, claims 49 and 51 are rejected.

***Allowable Subject Matter***

8. Claims 44-46 and 52-53 contain allowable subject matter.

9. The following is a statement of reasons for the indication of allowable subject matter: Johnson et al. (WO 03/084610, published 16 October 2003) report the closest prior art. LY 404039, discussed above, differs from the structure of claims 44-46 and 52 because variable A is alanyl. In claims 44-46 and 52, variable A is methionyl.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

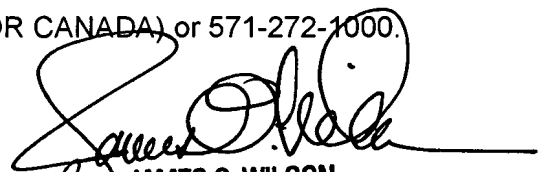
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Noble Jarrell /NJ/

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